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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/689,217

10/20/2003

Georg Berger

3975.023

8950

30448

7590

06/14/2007

AKERMAN SENTERFITT

P.O. BOX 3188

WEST PALM BEACH, FL 33402-3188

EXAMINER

AZPURU, CARLOS A

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

06/14/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/689,217	Applicant(s) BERGER ET AL.	
	Examiner Carlos A. Azpuru	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3192004&4192004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the information disclosure statement filed
04/19/2007.

Election/Restrictions

Claims 21-25 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 04/10/2007.

Applicant's election without traverse of 1-20 in the reply filed on 04/10/2007 is acknowledged.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 7,223,420 (US'420). Although the conflicting claims are not identical, they are not patentably distinct from each other because US'420 claims a resorbable calcium phosphate biocement having the same P-NMR measurements, Q-groups of orthophosphate and disphosphate, same components of a secondary phase; X-ray diffractometric measurements and components; as well as the same X-Ray amorphous phases. The percentages of each are also identically claimed (see claim 1). Where the claims differ however is claimed particle size distribution. While the instant claims do not set this out, processing of the particles is largely determined by the makeup of the calcium phosphate manufactured. As such, their compression characteristics would be identical. The selection of particle distribution would then be within the skill of the ordinary practitioner depending on the desired optimal particle size and could be accomplished by any art recognized method of manufacturing particles. As such, the instant claims would have been obvious to one of ordinary skill at the time of invention given the claims of US'420.

Claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 10/689,219 (US'219). Although the conflicting claims are not identical, they are not patentably distinct from each other because US'219 claims a

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bone replacement comprising crystalline and X-Ray amorphous phases characterized by the same P-NMR measurements, Q-groups of orthophosphate and disphosphate, components of a secondary phase; X-ray diffractometric measurements and components; as well as the X-Ray amorphous phases. The percentages of each are also overlap and are within the range as set out in US'219 (see claim 1). Those of ordinary skill would have expected similar bone replacement characteristics for the composition. The instant claims would have been obvious to one of ordinary skill in the art at the time of invention given the claims of US'219.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 91/07357 (Berger et al).

Berger et al disclose a porous, rapidly soluble glass ceramic comprising the same components of the instantly claimed crystalline phase which is used as a bone

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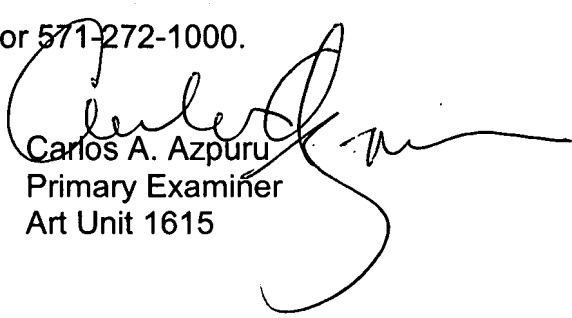
replacement composition (see Abstract; Claim 7). In particular, claim 7 sets out the same raw materials as claimed herein. Berger forms a crystalline and amorphous phase. Processing of the material appears to utilize heat melting of the materials. It is therefore the position of this examiner, that those of ordinary skill would have expected not only the same composition characteristics from the workup of these materials as taught by Berger et al, but also the same bone replacement effects. The instant claims would have been obvious to one of ordinary skill in the art at the time of invention given the material and processing steps as disclosed by Berger et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Carlos A. Azpuru
Primary Examiner
Art Unit 1615

ca



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,221	10/20/2003	Georg Berger	3975.025	4078
7590 02/10/2006 Stephan A. Pendorf Pendorf & Cutliff 5111 Memorial Highway Tampa, FL 33634-7356			EXAMINER ARNOLD, ERNST V	
			ART UNIT 1616	PAPER NUMBER

DATE MAILED: 02/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/689,221		BERGER ET AL.	
	Examiner		Art Unit	
	Ernst V. Arnold		1616	

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

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- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 14-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

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| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>4/19/2004</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

The Examiner acknowledges receipt of Applicant's response to the restriction requirement filed on 12/30/05. Applicant elected Group I, claims 1-13 with traverse. Applicant argued that the hydroxyapatite is not within the crystal phases of part b) of claim 1; namely $\text{Ca}_2\text{KNa}(\text{PO}_4)_2$, $\text{Ca}_{10}\text{Na}(\text{PO}_4)_7$, and $\text{Ca}_{10}\text{K}(\text{PO}_4)_7$. Also, Applicant argued that the composition made by mixing hydroxyapatite and CaHPO_4 to make a biocement would not include a key component of the instant invention; namely diphosphates such as $\text{Na}_2\text{CaP}_2\text{O}_7$, $\text{K}_2\text{CaP}_2\text{O}_7$, and $\text{Ca}_2\text{P}_2\text{O}_7$. The Examiner has carefully considered these arguments. However, the Examiner maintains that the instant composition can be made by a reasonable alternative method; namely *separately* preparing $\text{Ca}_2\text{K}_{1-x}\text{Na}_{1+x}(\text{PO}_4)_2$, where $x = 0.1$ to 0.9 , $\text{Ca}_{10}\text{Na}(\text{PO}_4)_7$, $\text{Ca}_{10}\text{K}(\text{PO}_4)_7$; adding the proper amount of $\text{Na}_2\text{CaP}_2\text{O}_7$, $\text{K}_2\text{CaP}_2\text{O}_7$, $\text{Ca}_2\text{P}_2\text{O}_7$, NaPO_3 , KPO_3 and mixtures thereof to arrive at the instantly specified ratios and mixing the powder. Therefore, the restriction requirement is maintained and made final.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claims 1-13 are presented for examination on the merits. Claims 14-21 are withdrawn from consideration as being drawn to non-elected subject matter.

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Applicant is advised of the use of proper Markush language in instant claim 2 which reads more clearly as: ...by weight chain phosphates selected from the group consisting of...

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-13 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for combining specific amounts of CaO, P₂O₅, Na₂O, K₂O, MgO and SiO₂, homogenizing and drying the mixture and subjecting it to a step by step thermal treatment lasting 1-2 h at 350-450 C, 750-850 C, and 950-1050 C respectively, melting the mixture at between 1550 and 1650 C holding at the melting temperature for between 10 and 60 minutes and finally cooling the mixture in a spontaneous or temperature controlled manner and then grinding it to a specific particle range ([00034]), does not reasonably provide enablement for melting and grinding any powder and obtaining the proper ³¹P-NMR and X-ray diffraction measurements. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re

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Wands, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: 1) scope or breadth of the claims; 2) nature of the invention; 3) relative level of skill possessed by one of ordinary skill in the art; 4) state of, or the amount of knowledge in, the prior art; 5) level or degree of predictability, or a lack thereof, in the art; 6) amount of guidance or direction provided by the inventor; 7) presence or absence of working examples; and 8) quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure. When the above factors are weighed, it is the Examiner's position that one skilled in the art could not practice the invention without undue experimentation.

1) Scope or breadth of the claims

The claims are broader in scope than the enabling disclosure. The specification discloses that combining specific amounts of CaO, P₂O₅, Na₂O, K₂O, MgO and SiO₂, homogenizing and drying the mixture and subjecting it to a step by step thermal treatment lasting 1-2 h at 350-450 C, 750-850 C, and 950-1050 C respectively, melting the mixture at between 1550 and 1650 C holding at the melting temperature for between 10 and 60 minutes and finally cooling the mixture in a spontaneous or temperature controlled manner and then grinding it to a specific particle range ([00034]), does not reasonably provide enablement for melting and grinding any powder and obtaining the proper ³¹P-NMR and X-ray diffraction measurements. However, Applicant is purporting to use any powder and analyze the products with ³¹P-NMR and X-ray diffraction.